

Post-Market Surveillance Methods for AI in Radiology

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February 25, 2020

Talk Takeaway

Problem

Safety and efficacy of AI software in radiology cannot be ensured exclusively through pre-market testing



Solution

Post-market surveillance designed to empower intended users to determine whether AI medical devices actually work for them

Central Question

How should we ensure that AI-based radiology software is safe and effective in the real-world?

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*Pre-market
Testing*

*Post-market
Surveillance*

Standalone Testing
Reader Study

Adverse Event Reporting

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*Pre-market
Testing*

How should we ensure that AI-based radiology software is safe and effective in the real-world?

*Pre-market
Testing*

Day 1

Day 2 ... 8,000?

Underlying Problem

AI “agents” are taking actions in a complex, dynamic environment using imperfect information



Safety and efficacy of the AI throughout its deployment cannot be ensured exclusively through pre-market testing



Adverse event reporting is not enough

AI Software Requires Strong Post-market Surveillance

Illustrative Example: Self-Driving Cars



AI Software Requires Strong Post-Market Surveillance

Practical Limitations of Pre-market Testing

46,000+

Healthcare Facilities

883,000,000+

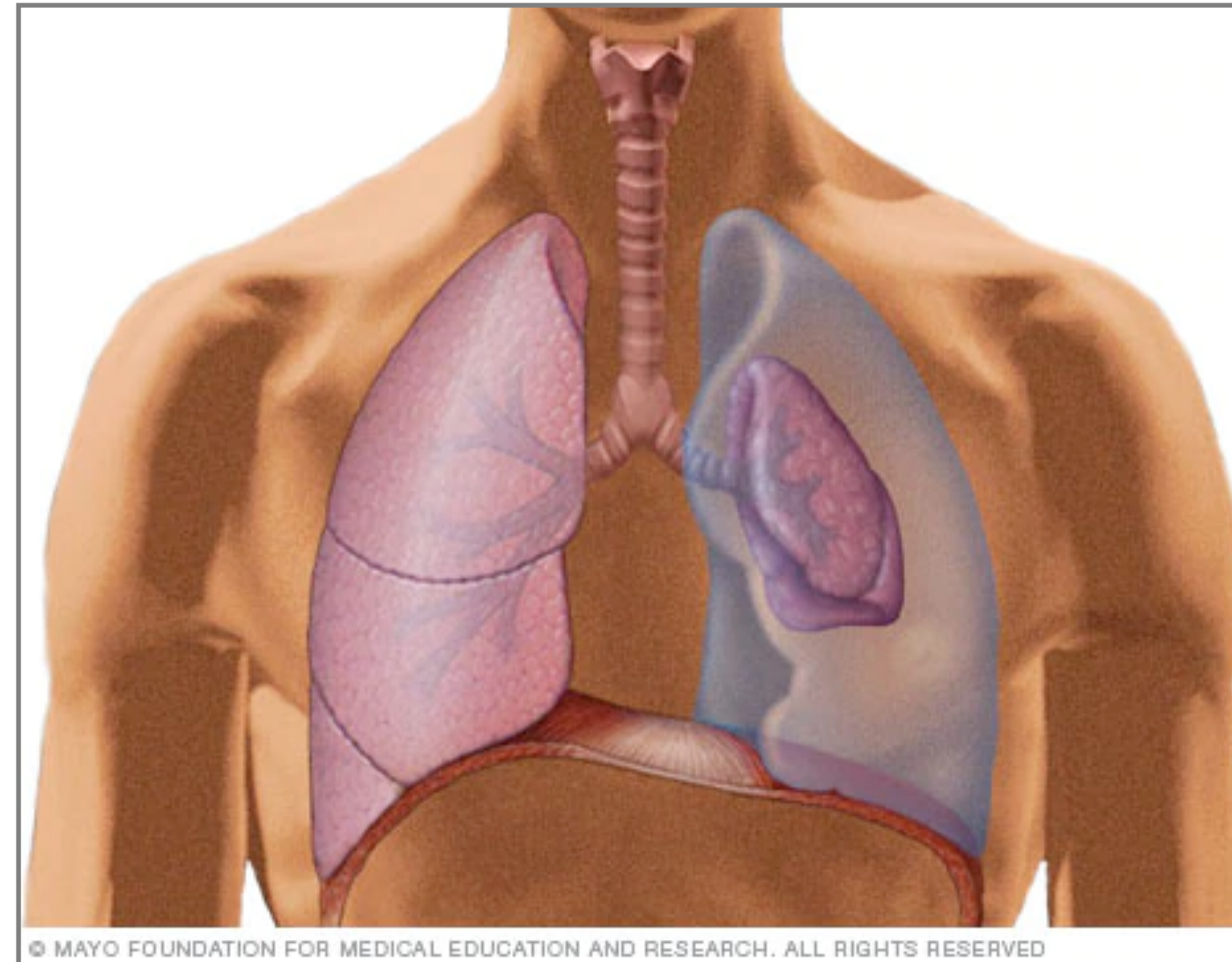
Annual Patient Visits

1,300,000+

Clinical Providers

AI Software Requires Strong Post-Market Surveillance

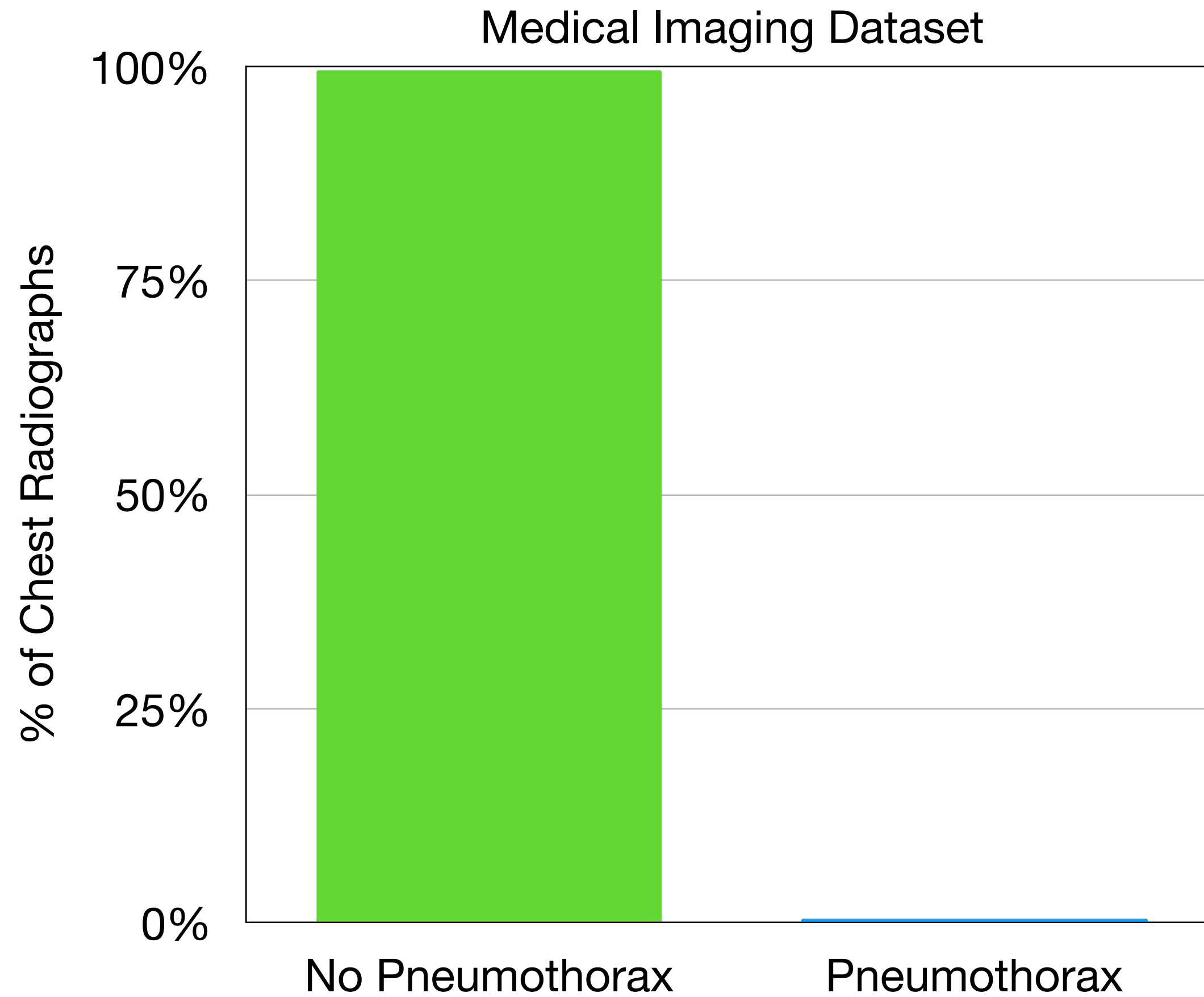
Illustrative Example: Pneumothorax Detection on Radiographs



Pneumothorax

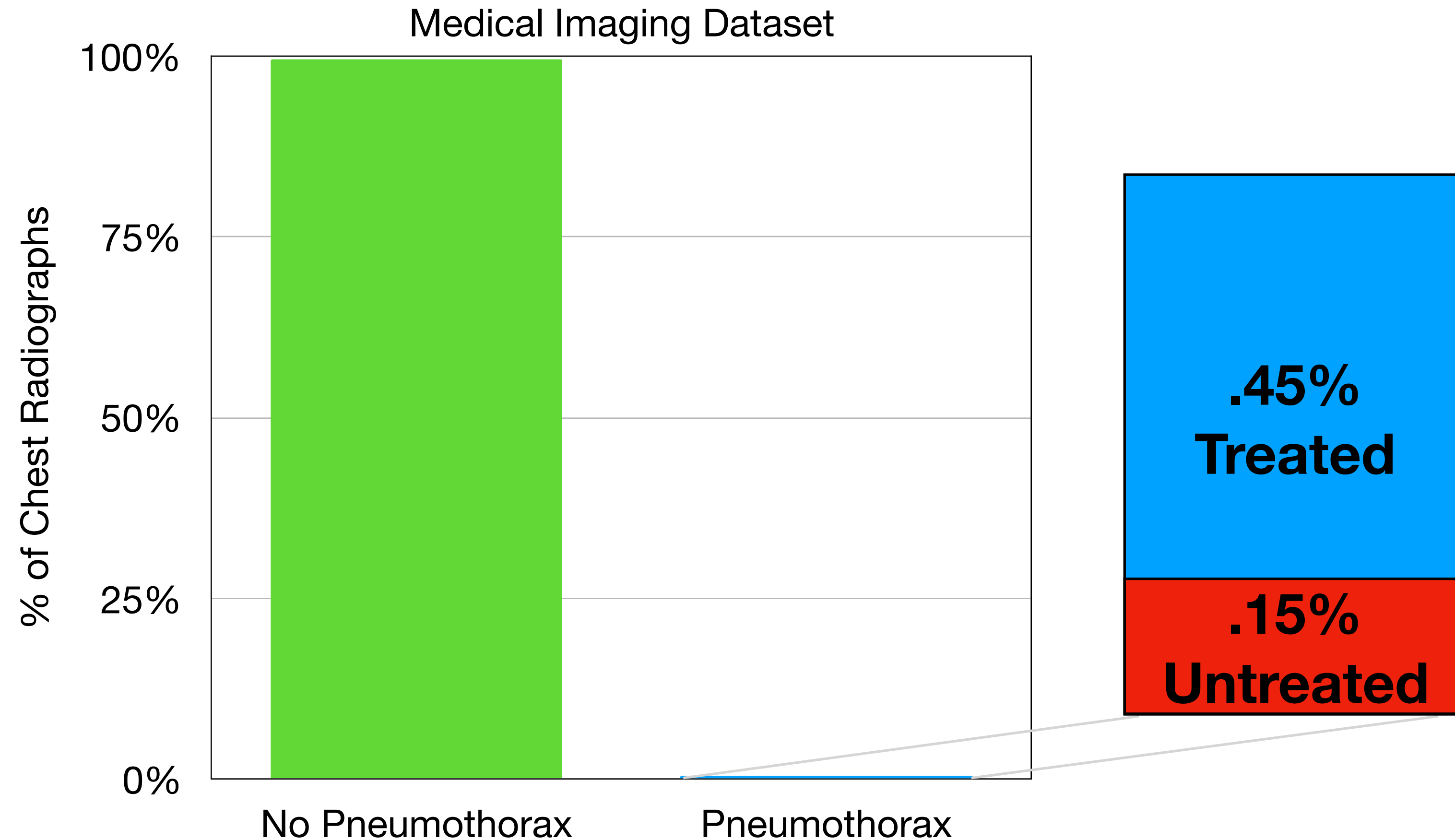
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Illustrative Example: Pneumothorax Detection on Radiographs



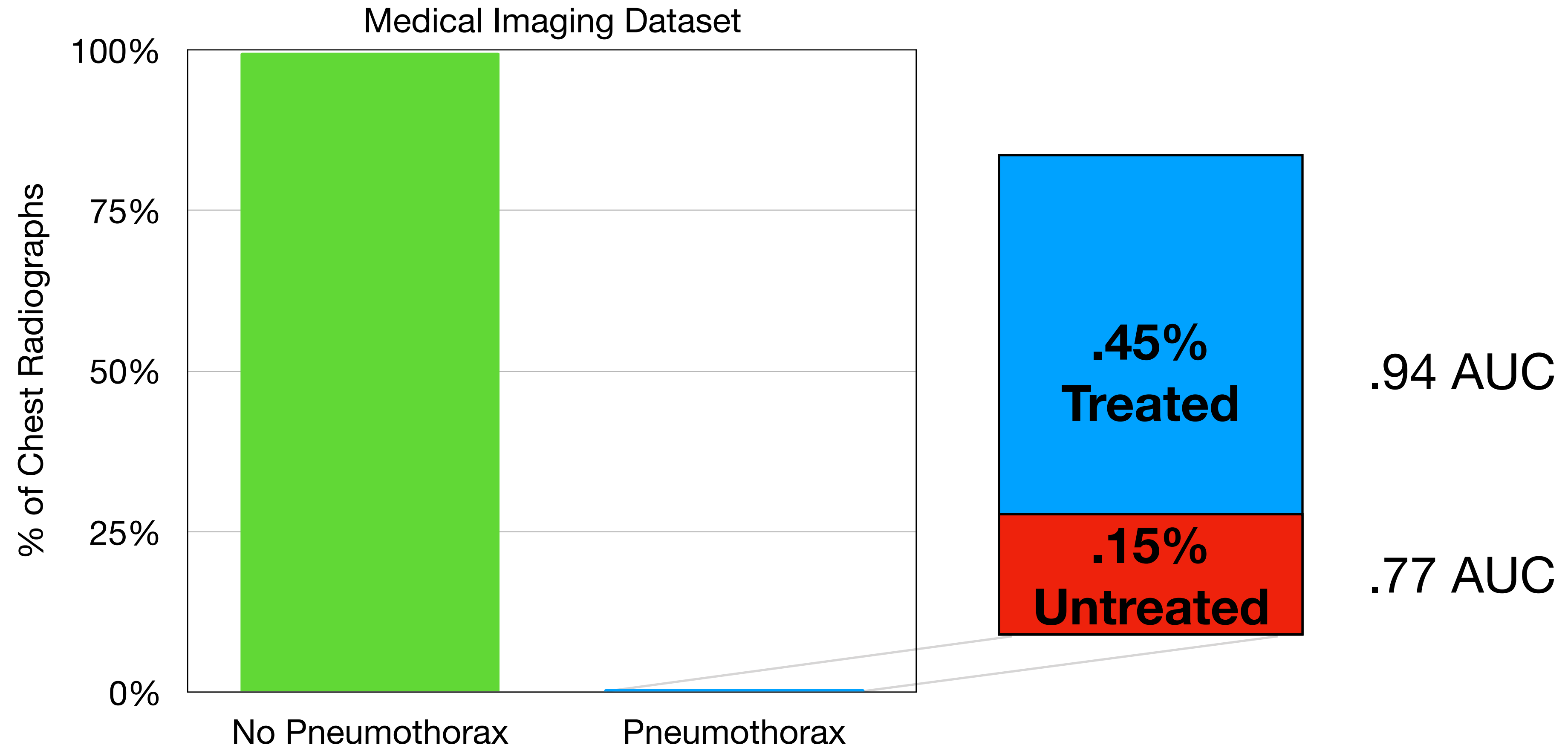
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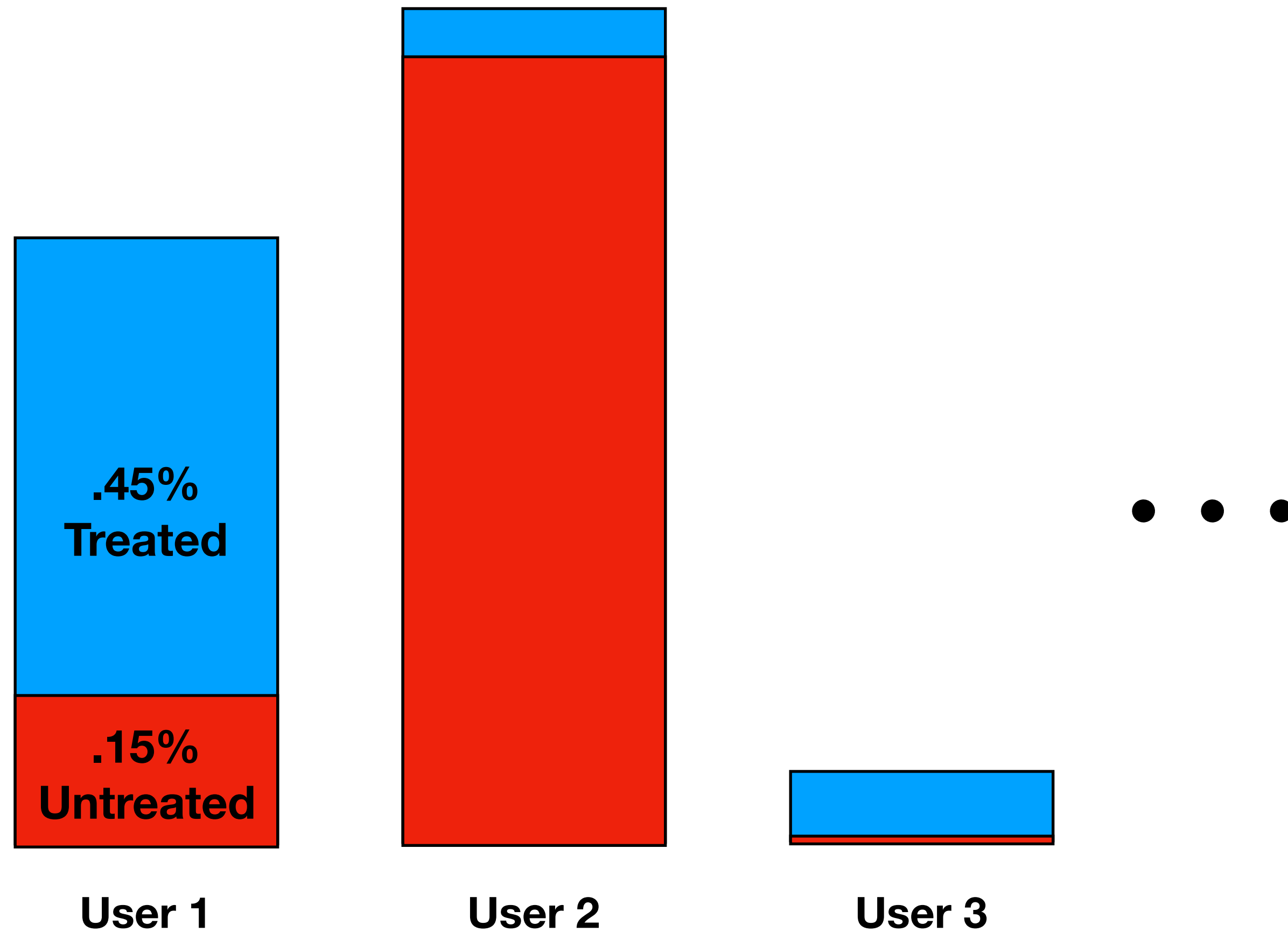
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Illustrative Example: Pneumothorax Detection on Radiographs



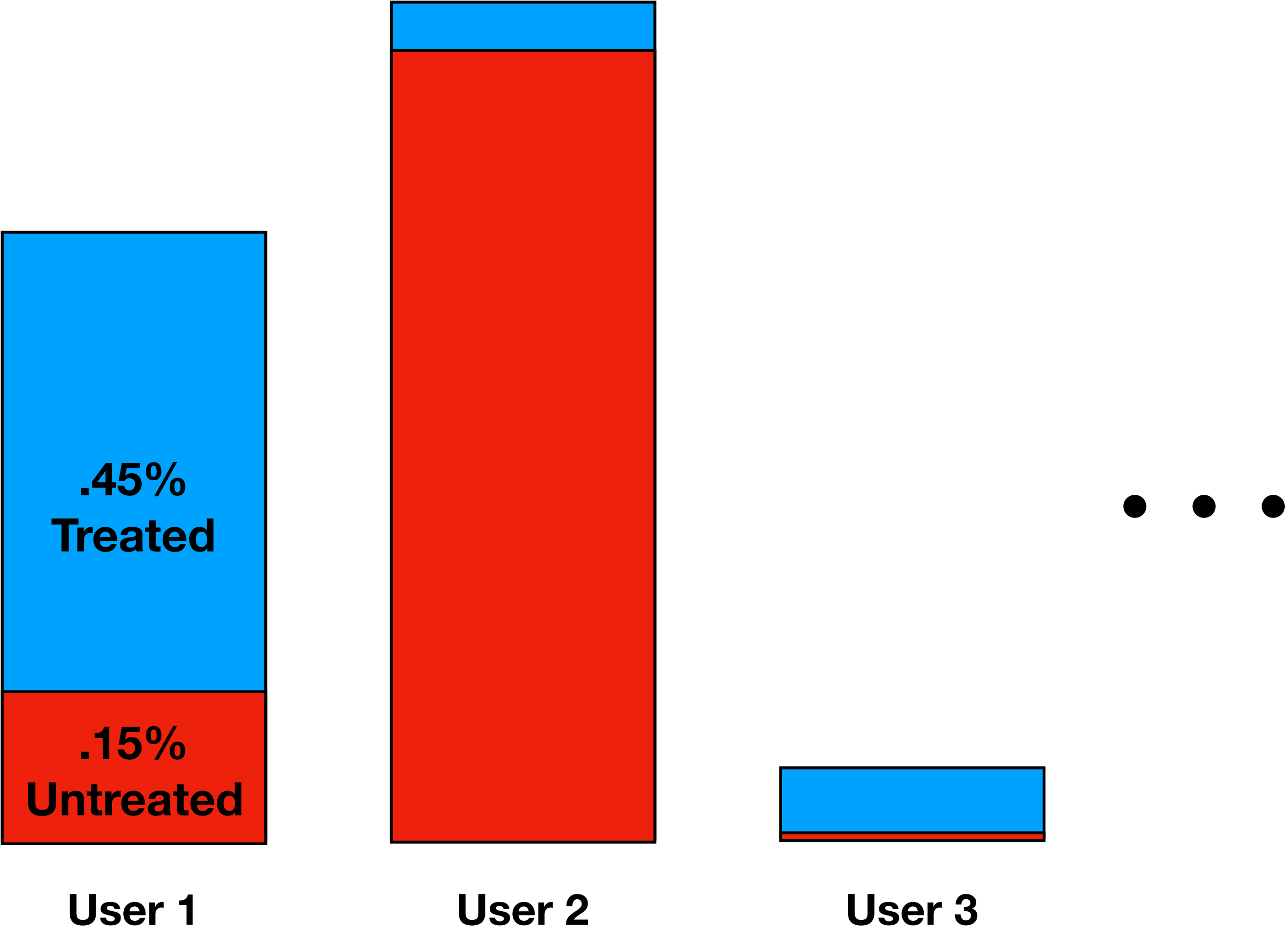
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AI Software Requires Strong Post-Market Surveillance

Illustrative Example: Pneumothorax Detection on Radiographs



Risks Specific to AI Devices

- Hidden confounders
- Distributional shifts in patient populations, imagery, etc.
- Poor interpretability
- ...

Strong Post-Market Surveillance: Individualized Testing

How does society ensure that drivers operating motor vehicles are safe and effective?

Strong Post-Market Surveillance: Individualized Testing



Society forces each individual to take a driving test

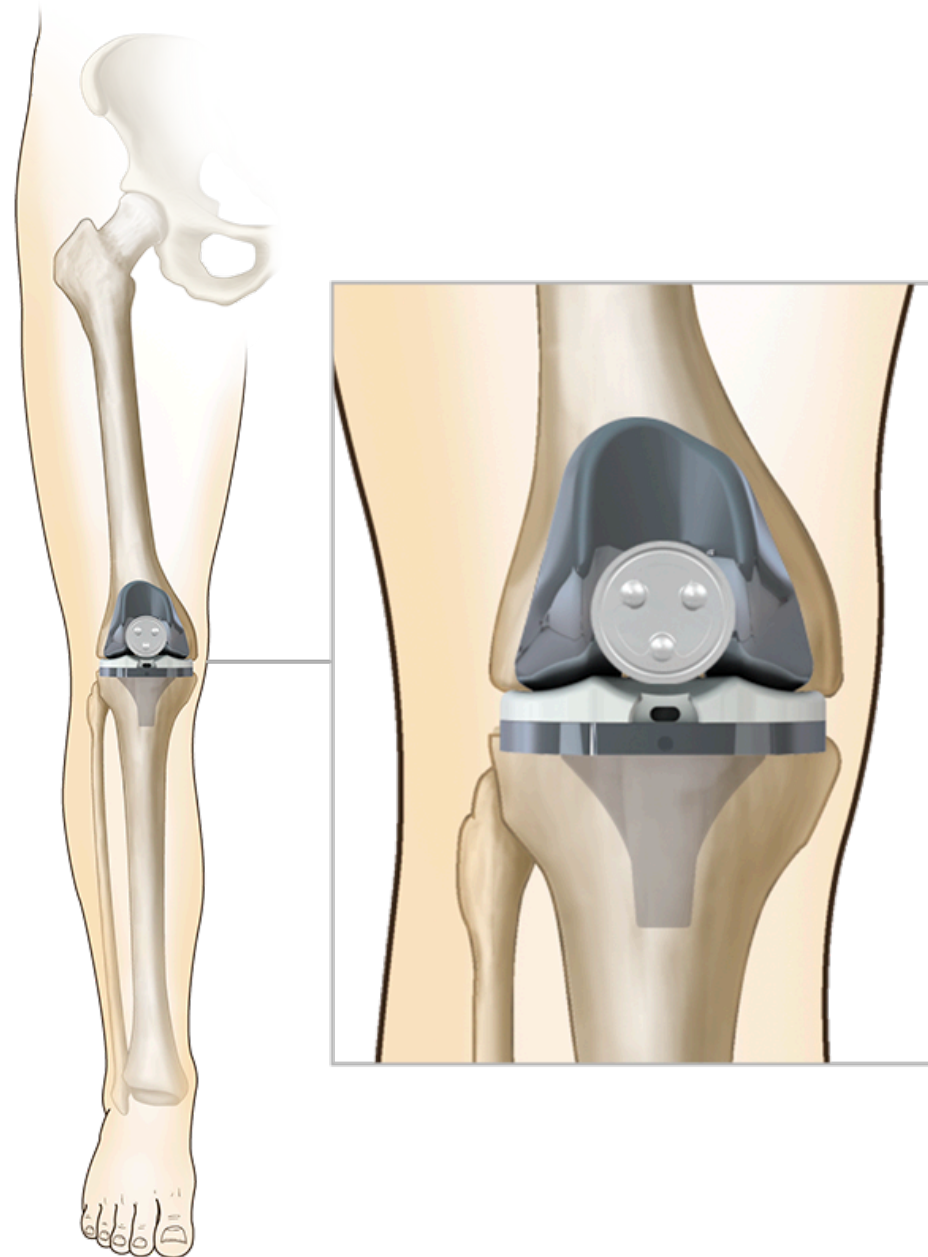
Rather than test a small subset of the population and extrapolate their performance to **all** drivers

Strong Post-Market Surveillance: Individualized Testing



Society forces each individual to take a driving test

Rather than test a small subset of the population and extrapolate their performance to **all** drivers



An equivalent of the driving test isn't possible for most medical devices

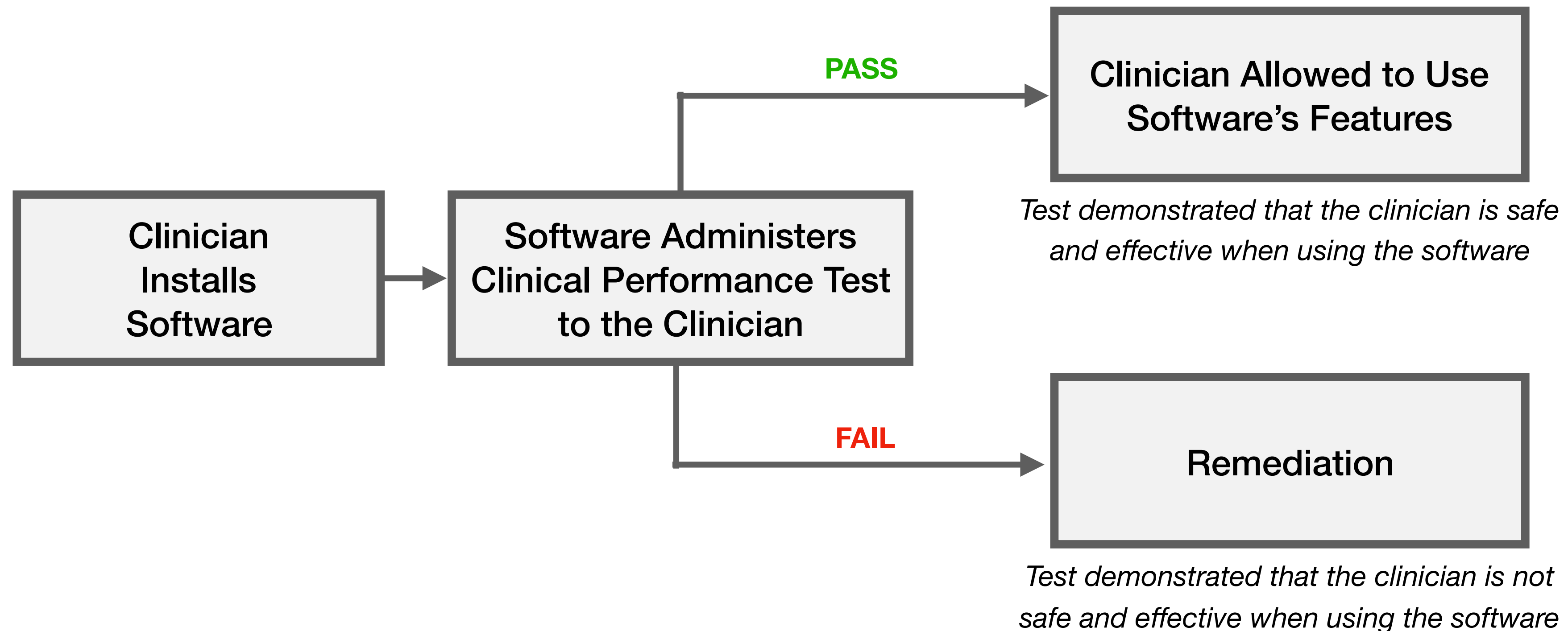
Individualized testing would cause harm to patients and be impractical and costly

Strong Post-Market Surveillance: Individualized Testing

An equivalent of the driving test is feasible for
most software devices in radiology

Strong Post-Market Surveillance: Individualized Testing

A test of efficacy can be embedded within the software with no risk or cost to patients



Provides evidence that *every* “credentialed” user benefits from it

Strong Post-Market Surveillance: Individualized Testing

No need to test a small subset of the population and extrapolate their performance to all users

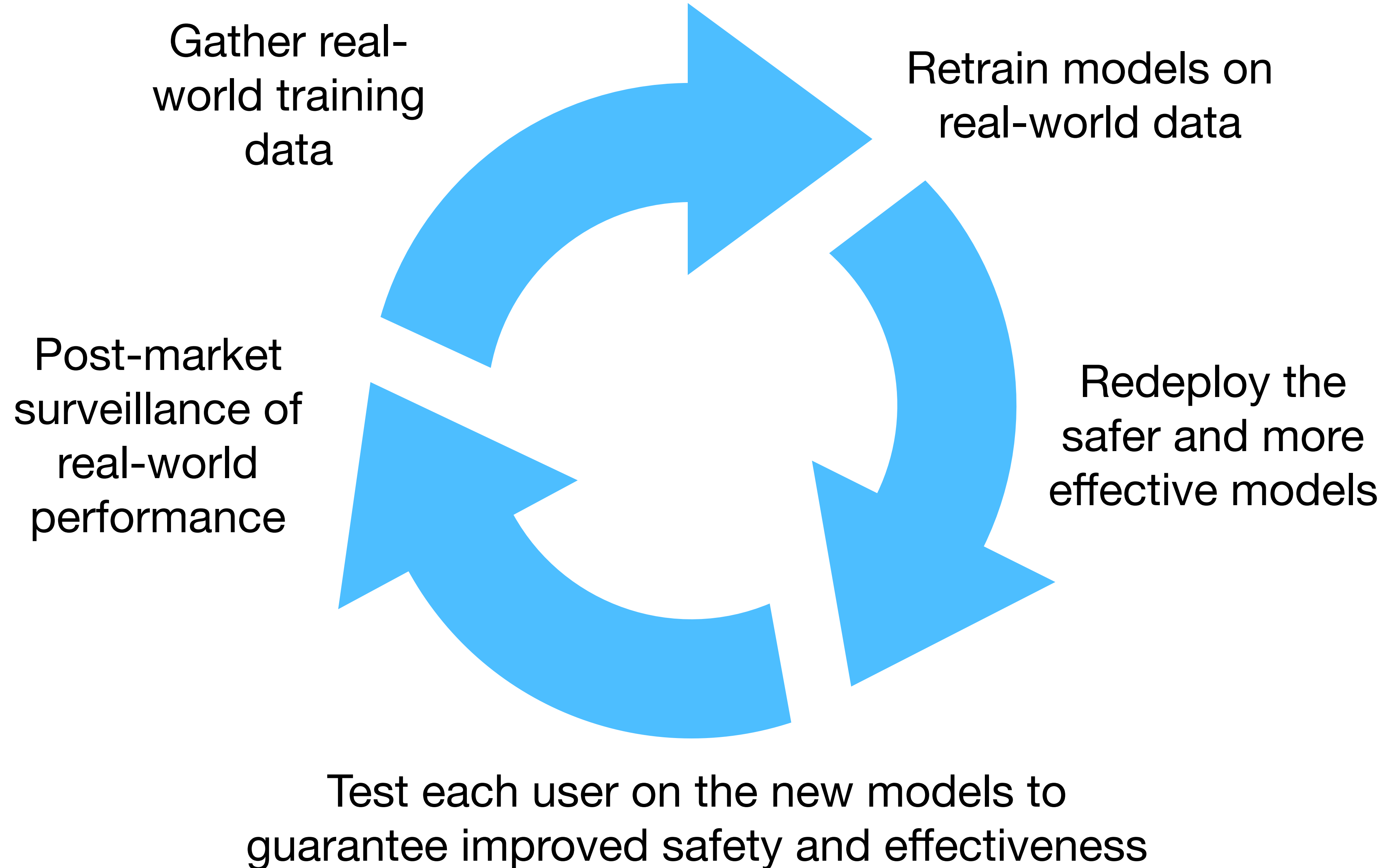


Individualized testing has no risk to patients because it can be retrospective and administered to intended users



Individualized testing would be practical and inexpensive due to the scalable nature of software

Future Directions



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